Remarks

Claims 1-4, 7-11, 30, 31, 34-36, 42, 43, 49, 55, 59, and 64 are pending in the application. Claims 1 and 42 have been amended by incorporating the subject matter of Claims 2, 3, 33, and 34 into Claim 1 and by incorporating the subject matter of Claim 7 into Claims 1 and 42. Consequently, Claims 2, 3, 7, 33 and 34 have been cancelled without prejudice or without admitting anticipation or obviousness. Claims 8 and 35 have been amended to provide proper antecedent basis.

§112 Rejections

I. Claims 1-4, 7-11, 30, 31, 34-36, 42, 43, 49, 55, 59 and 64 were rejected under USC §112, first paragraph for non-enablement over the scope of the claims.

Examiner asserts that the claims as a whole are enabling for compounds wherein R^1 and R^0 and aryl(phenyl) with halogen or methoxy substituents or R^4 is an alkyl, halo-substituted alkyl, or cycloalkyl, but not enabled for the other substituents. Firstly, Examiner ignored the example illustrating a cyano-substituted phenyl (Ex. No. 1A-2). More importantly, Examiner appears to be restricting Applicants invention to only those compounds specifically exemplified which is totally improper. It has never been the law that an Applicant is restricted to only those compounds exemplified in the specification. In fact, there is no requirement that any examples be present. One must only provide sufficient teaching to allow one of skill in the art to practice the invention. Controlling precedent requires that the US PTO accept the objective truth of Applicants' teachings of enablement unless there is a reason to doubt these teachings. Applicants respectfully submit that there is no reason to doubt the objective truth of the statements contained within the Specification upon which Applicants rely for enabling support.

> As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing the defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for the enabling support. In Re Marzocchi, 439 F.2d 220,222 (CCPA 1971).

The burden is on the Examiner to come forward with *evidence* as to why assertions of utility should not be accepted. In the instant case, the Examiner has merely made conclusory statements from general references without any specific evidence why Applicant's assertions should not be accepted as true. Examiner has totally ignored the references cited in the IDS which establish the present skill of the art. For example, Applicants can rely on earlier work by the same assignee to support the additional substituents. See, e.g., US 7,129,239 (Pfizer, Inc.) which describes numerous R^0 and R^1 substituents. Without specific evidence refutting the state of the art, the rejection of the specification/claims under 35 USC §112, 1st paragraph for lack of enablement is contrary to well established law.

In the advisory action, Examiner raised issues with respect to enablement of heterogroups and enablement of the method of treating obesity. Again, the Examiner is merely making conclusory statements without any evidence to support her non-enablement assertion. However, in order to move the application to allowance, Applicant provides below more detailed information in support of his position of patentability of the present claims.

First, with respect to the heterogroups, it is assumed that the Examiner is concerned with the heterogroups listed in R^4 since the heteroaryl groups listed for R^0 and R^1 have been deleted through amendment. As part of the enablement requirement, it is well-established that one does not have to provide exemplification of every compound that falls within the scope of the claims. Clearly, it is well within the skill of the art to make compounds where R^4 is a piperidin-1-yl, pyrrolidin-1-yl, or morpholin-4-yl based on the teachings in Schemes I-VII (through introduction of the R^4 group where the reagent R^4NH_2 is 4-aminopiperidine, 4-aminopyrrolidine and 1-aminomorpholine). 4-aminopiperidine and 4-aminopyrrolidine are available commercially and 1-aminomorpholine may be prepared synthetically, e.g. *via* the synthesis described in Schönafinger, K., Il Farmaco, **54**, 316-320 (1999). The Examiner has provided no substantiated evidence to the contrary.

With respect to the utility rejection, again the Examiner has provided no credible evidence to refute Applicant's assertions of utility, in particular, for the treatment of obesity. Applicant would like to draw the Examiner's attention to lines 25-26 of page 52 of the specification. CB-1 binding activities of 4 nM and 2nM were observed for Examples 1A-2 and 1A-3, respectively. The binding activities were determined using a competitive binding assay to detect compounds that inhibit the binding of [^{3}H] SR141716A (a known selective radiolabeled CB-1 ligand) which is

described on pages 53-55 of the specification. SR141716A, also known as rimonabant (Acomplia™), is currently being sold commercially by Sanofi-Aventis in Europe for the treatment of obesity. Applicants specifically state that the "...compounds of Formula (I) and (II) ..act as cannabinoid receptor ligands (in particular, CB1 receptor antagonists)." Page 3, lines 17-18, and page 8, lines 3-4. It was well-known in the art at the time of filing the present application that CB-1 antagonists (including rimonabant) were useful in the treatment of Obesity. See, e.g., Colombo, G., et al., "Appetite Suppression and Weight Loss after the Cannabinoid Antagonist SR141716," Life Sci, **63**, PL113-PL117 (1998); and Pertwee, R.G., "Pharmacology of Cannabinoid Receptor Ligands" Curr Med Chem, **6**, 635-664 (1999). Both of these articles are of record in the IDS entered on July 29, 2004 and acknowledged by the Examiner on September 14, 2005. Since the present compounds act as CB-1 antagonists, then clearly the compounds would be useful for the treatment of Obesity. Examiner has provided no credible evidence to the contrary.

Applicants respectfully submit that the amended claims and the claims dependent thereon are in condition for allowance.

Respectfully Submitted:

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